

APR 12 1996

K955251

Premarket Notification

510(k) Summary

[As required by 21CFR 807.92(a)]

Trade Name: Nasa II C-arm

Common Name: C-arm

Classification Name: Mobile X-ray System

I certify that, in my capacity as President of Imaging Services, Inc., The Nasa II C-arm is equivalent to the OEC 901 and 902 model C-arms. Mechanically and electrically the Nasa II C-arm is as safe and effective as the OEC models 901 and 902. The difference between OEC's above models and the Nasa II is the imaging chain or CCD Camera and Camera Control Unit. The intended use for the Nasa II has not change and is not marketed as such.

The OEC 902 C-Arm frame, X-Ray Generator, X-Ray Control, Control Panel, Electrical Systems remain the same. Imaging Services, Inc. takes an OEC 902 and repaints it. We repair all mechanical brakes, replace the wheels with the new wheels rated for a greater weight, repair or replace motor drive assemblies with original or comparable replacement parts, repair all electronic systems, then calibrate the X-Ray generator to manufacture specifications using the OEC 902 Service Manual. Then we add a new 9/6 Image Intensifier and CCD Camera system. The CCD Camera System is calibrated to North American Imaging and Imaging Services Specifications. The ABS system utilizes original manufacturer's specifications, wiring and its electronic path remains the same.

The wiring of the CCD Camera system uses original wires provided by the original camera system which was deinstalled. The interface between the C-Arm and monitor cart also utilizes existing wiring as well as spares provided by OEC when the unit was originally manufactured.

Imaging Services, Inc. then tests the system to comply with all Federal, State and BRH standards. In no way does the final product effect the original X-Ray control as designed by OEC. As stated above, we continue to utilize the original C-Arm Generator and Control System as intended by OEC Disonics.

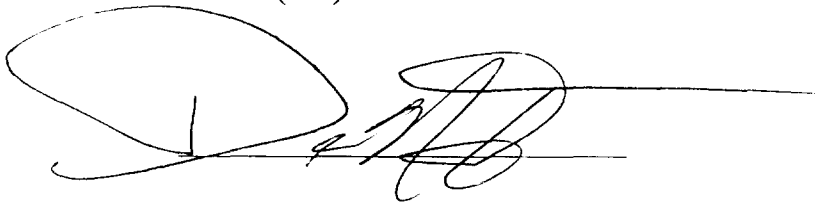
This upgraded version is designed only to provide a refurbished C-Arm with state of the art image quality. All of the results from this upgrade improve the final product delivered to the customer. Also with the CCD Camera upgrade and new Image Intensifier, the dynamic range of the C-Arm is increased to new C-Arm standards.

Patient dose is decreased by improving dynamic range and contrast/resolution is increased by the CCD Camera upgrade.

Imaging Services, Inc. follows all guidelines of Good Manufactures practices including serial number and calibration tracking and verification. All calibration equipment used by Imaging Services, Inc. is traceable to the National Bureau of Standards. Calibration specifications guidelines for x-ray control and generation are followed from the original Manufacturer's Service Manual. Imaging Chain Calibration Specifications/ Guidelines are followed by North American Imaging and Imaging Services, Inc. standards.

This product provides a high end, low cost refurbished system to customers who cannot afford a new C-Arm, while maintaining superior image quality as with a new C-Arm.

Imaging Services, Inc.
1037 N. Lima Street
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A handwritten signature in black ink, appearing to read 'D. Janes', with a long horizontal line extending to the right.

Dean N. Janes President

2/16/96

K 955251
(Premarket Notification [510(k)] number)